OCT 11 2002

Taiwan Electronic Data Processing Corporation

510(k) Summary of Safety and Effectiveness

K022710

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
August 8, 2002

Submitter's Information: 21 CFR 807.92(a)(1)
Taiwan Electronic Data Processing Corporation
3rd Floor, No. 2, Lane 7, Pao-Kuo Road
Hsin-Tien City, Taipei Hsien
Taiwan, Republic of China

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	SMARTPACS™
Common Name:	Picture Archiving Communications System
Device Classification Name:	892.2050
	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K002936
Device Name	MODIFICATION TO IDS5 IMAGE DISPLAY SYSTEM
Applicant	SECTRA-IMTEC AB
Product Code	LLZ
Date Received	09/21/2000
Decision Date	10/17/2000
Decision	SUBSTANTIALLY EQUIVALENT (SE)

Device Description: 21 CFR 807 92(a)(4)
The SmartPACS™ system is a server-based software application.

Smart PACS (SP) is a distributed image management system that manages the archival, retrieval, and distribution of medical images within a Picture Archiving and Communication System (PACS) environment.

The SP system provides online access to patients' current and historical radiological images and relevant examination data. The system is designed for facilitating the clinical practice of radiologists and physicians.

The SP system implementation is based on the Digital Imaging and Communication in Medicine (DICOM) standard. The standard allows communications of images and relevant information such as patient demographics and examination data between the system and other DICOM-compliant imaging devices such as CT scanners, MR imager, CR systems, and image viewing workstations.

Indications for Use: 21 CFR 807 92(a)(5)

The SmartPACS™ device is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstations, image storage and printing devices using DICOM or similar standards.

Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is a software server application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for SmartPACS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device SmartPACS™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Taiwan Electronic Data
Processing Corporation
% Mr. Carl Alletto
1100 Lakeview Blvd.
DENTON TX 76208

Re: K022710
Trade/Device Name: SmartPACS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 22, 2002
Received: August 14, 2002

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Taiwan Electronic Data Processing Corporation

(Indications for Use Form)

510(k) Number: K022710

Device Name:
SmartPACS™ system

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022710